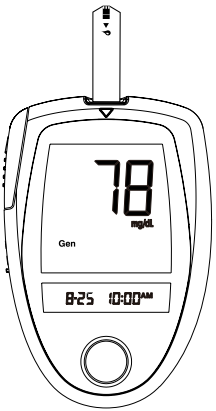
UltraTRAK™ PRO

BLOOD GLUCOSE MONITORING SYSTEM



OWNER'S MANUAL

311-4255100-001
Version 1.0 Octorber, 2008

Dear UltraTRAK PRO System Owner:
This manual contains important information you must know about the system. Please read it thoroughly and carefully.

UltraTRAK PRO boasts Autocode capabilities, requiring no coding for healthcare professionals and patients. What this means is fewer steps during the testing process, and no risk of false readings because of errors related to incorrect coding.

UltraTRAK PRO also has a top-loading strip port with strip ejection capabilities, ensuring optimal safety for healthcare providers and convenience. The strip eject function eliminates any blood contamination dangers associated with manually releasing a strip, offering the safest disposal possible.

Additionally, UltraTRAK PRO allows you to store your control solution testing results, allowing healthcare providers to be adept with the recommended control testing process. The system also has 4 alarm settings – this thoughtful design helps you routinely check your daily blood glucose on time.

IMPORTANT SAFETY INSTRUCTIONS
READ THIS BEFORE USING

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this manual.
3. Do not use accessories which are not supplied by the manufacturer.
4. Do not let the equipment or its flexible cord come into contact with surfaces which are too hot to touch.
5. Do not use the equipment where aerosol sprays are being used, or where oxygen is being administered.
6. Do not use device if it is not working properly, or if it has suffered any damage.
7. Before using product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.

KEEP THESE INSTRUCTIONS

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◉ IMPORTANT INFORMATION

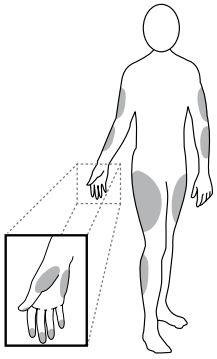
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If you get your blood glucose results lower or higher than usual, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.
- Apply only capillary whole blood sample to test your blood glucose. Applying other substances will cause wrong results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Please refer to your test strip package insert for additional important.

◉ ABOUT ALTERNATIVE SITE TESTING (AST)

Important: There're limitations for doing AST.
Please consult your healthcare professional before you do AST.

What is AST?

Alternate site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. UltraTRAK PRO Test Strips allow you to test on the palm, the forearm, the upper arm, the calf, and the thigh with the equivalent results to fingertip testing



What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings weren't so condensed, you won't feel as much pain as at the fingertip.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, **take blood sample from your finger only.**

We strongly recommend you do AST in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- you think your blood glucose is low.
- you are unawareness of hypoglycemia.
- your AST results do not match the way you feel.
- you are testing for hyperglycemia.
- your routine glucose results are often fluctuating.
- you are pregnant.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow suggestions below before getting a drop of blood:

- Rub the puncture site about 20 seconds before penetration.
- Use a clear cap (included in the kit) instead while setting the lancing device.

◉ GETTING STARTED

◈ Intended Use

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

AST in this system can be used only during steady-state blood glucose conditions described in the section of “About AST”.

This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

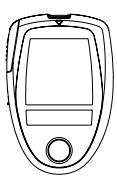
◈ Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

◈ Contents of the System

These products included in the kit have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only the same brand-name test strips and a control solution with the blood glucose meter.

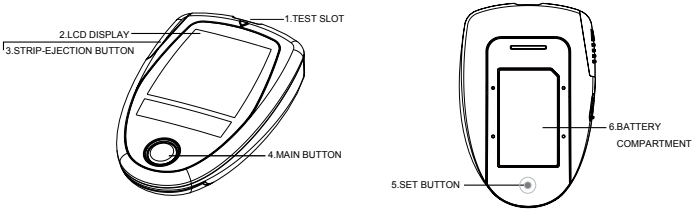
Your system includes:
① A meter ② Owner's manual
③ Warranty card ④ Your first time using guide
⑤ Daily log book ⑥ Carrying bag
⑦ Battery



PLEASE NOTE!

1. Please make sure that all products listed above are contained and sealed in the package before using this system. If you find any imperfection in our products, please return the whole system to the place of purchase.
2. Please note that strips, two other levels of control solutions (high and low), lancets, the lancing device and the clear cap for AST use are optional. Those are not included in the standard kit. Please contact the Customer Care Line at 1.888.90.VERTEX

◈ Appearance and Key Function of the Meter



1. TEST SLOT
Is where you insert the test strip. The meter will turn on automatically after insertion.

2. LCD DISPLAY
Guides you through the test using symbols and simple messages.

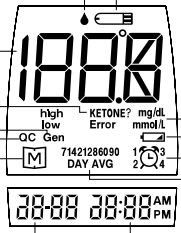
3. STRIP-EJECTION BUTTON
Is where the used strip will be ejected after you push up the button.

4 MAIN BUTTON
Located in front of the meter, the main white button is used to turn on the meter, enter the memory or control steps of setting.

5. SET BUTTON
Located in the battery compartment, is used to set up the meter.

6. BATTERY COMPARTMENT

◈ LCD Display



Blood Drop Symbol
Flashes when it is ready to apply the sample.

Test Result Area
Displays glucose results. A decimal point appears when the measurement unit is mmol/L.

Test Strip Symbol
Appears when the meter is turned on.

Measurement Unit
Appears with the test result either in mmol/L or in mg/dL.

Ketone Warning
Appears when the test result is equal or higher than 13.3mmol/L(240mg/dL).

Low Battery Symbol
Appears when the battery power is low.

Alarm Funtion Indicator
Appears when alarm are set. Four alarms can be set in this meter.

Measurement Mode

QC Symbol
Appears when doing a control test and indicates that result will be stored in the memory.

Date

Time

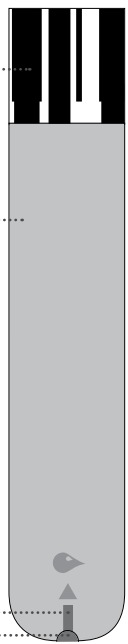
Day Average
Indicates that the displayed test result is an average.

Memory Symbol
Appears when you review the memory.

◈ Appearance of the Test Strip

This system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:



Contact Bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

Test Strip Handle
Hold this part to insert the test strip into the slot.

Confirmation Window
This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

Absorbent Hole
Apply a drop of blood here
the blood will be sucked automatically.

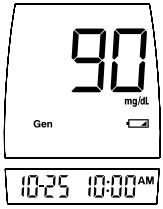
Please see pages 35~42, “Testing Your Blood”, for complete instructions.

◉ PREPARATION BEFORE USE

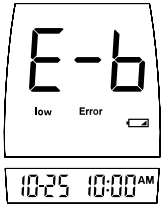
◈ Battery Replacement

Your meter comes with two 1.5V AAA alkaline batteries. The meter will alert you when the power is getting low by displaying two different messages:

1. When ▭ symbol appears on the display: the meter is functional and the result remains accurate, but it is time to change the battery.



2. With ▭ symbol, low and E-b symbols on the displays: the battery can not provide enough power for a test. You must change the battery immediately.



◆PLEASE NOTE!

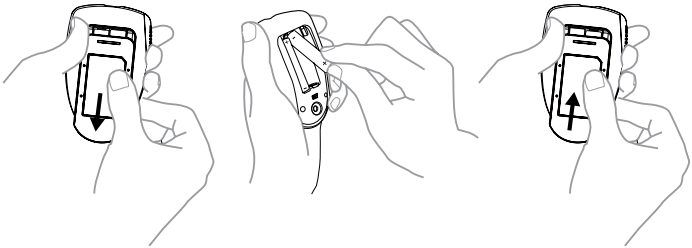
- Replacing the battery within 5 minutes does not affect the settings. Therefore, the settings do not need to be updated when the battery is changed.
- Batteries might leak chemicals if not used for a long time. Remove the battery if you are not going to use the device for an extended period (i.e., 3 months or more).
- Do not use the used battery. Use only the new one in required size and type.

To replace the battery, make sure that the meter is turned off.

STEP1 Press the buckle on battery cover and lift up to remove cover.

STEP2 Remove the old battery and replace with two 1.5V AAA alkaline batteries.

STEP3 Close the battery cover.



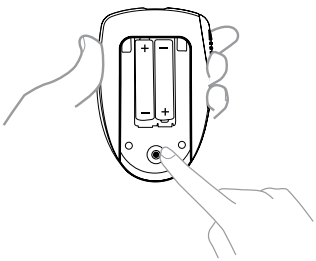
WARNING

As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.

◈ Setting the Meter and Deleting the Memory

Your meter comes with the time, date, unit of measurement, memory deletion and alarm function setting. If you need to set these parameters, please follow below steps.

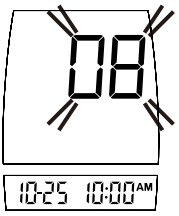
Start with the meter off. Then press the set button located in the battery compartment. The meter is now in the setting mode.



To set the time, you must first enter the setting mode. Start with the meter off. Then press the set button located in the battery compartment. The meter is now in the setting mode.

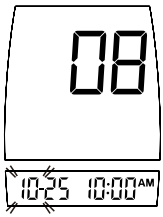
STEP 1 Set the Year

After pressing the set button, the year, a blinking number, will be shown on the screen firstly Press and release the main button to plus one year. You can also keep pushing down the main button to proceed faster. When the correct year is displayed screen, press the set button and then a flashing number, which stands for the month, is shown.



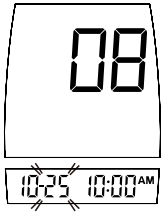
STEP 2 Set the Month

Press and release the main button until you see the correct month. To move faster, keep pushing the main button down. When the desired month is displayed, press the set button and then the day will flash.



STEP 3 Set the Day

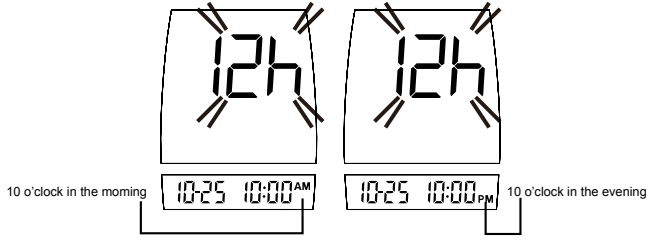
Press and release the main button until you see the correct day. To move faster, keep pushing the main button down. When the desired month is displayed, press the set button and then the hour will be shown on the screen.



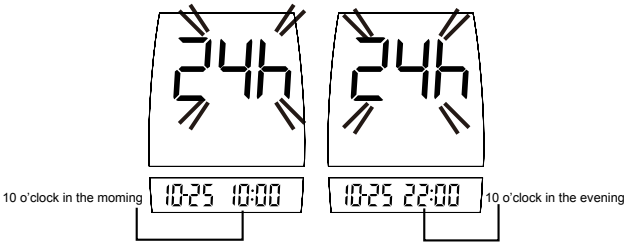
STEP 4 Select the 12h or 24h

Press and release the main button to select 12hor 24h. It differs in time presentation format.

If you select 12h, AM and PM will be shown together with time. An example is shown below.



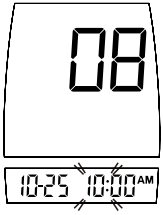
If you select 24h, format of time will be from 00:00 to 23:59 without AM and PM. An example is shown below.



After finishing setting 12h or 24h, press the set button and then the hour will flash on the screen.

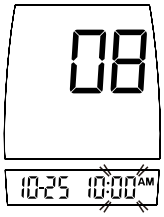
STEP 5 Set the Hour

Press and release the main button until you see the correct hour on the screen. To move faster, keep pushing the main button down. When the desired hour is displayed on the screen, press the set button and then the minute will flash.



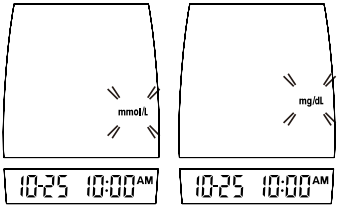
STEP 6 Set the Minutes

Press and release the main button to advance one minute. To move faster, keep pushing the main button down. When the desired minute is displayed, press the set button and then the current unit of measurement will flash.



STEP 7 Select mg/dL or mmol/L

Press and release the main button to select the unit of measurement you want to use is shown on the screen. Press the set button and the current unit of temperature will flash.

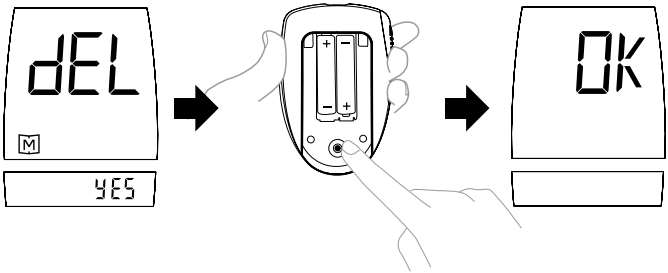


PLEASE NOTE!

The milligram per deciliter (mg/dL) is the standard unit in the United States. The millimole per liter (mmol/L) is the standard unit in Canada Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

STEP 8 Delete Memory

"dEL" and flashing yes/no is displayed on the screen. If you do NOT want to delete memory, press the main button to select "no" and then press set button to go to step 9. If you'd like to delete ALL memory, press main button to select "yes". Then press set button to delete All memory. "OK" is displayed in the meter, which means that all data stored is deleted. Go to step 9.



PLEASE NOTE!

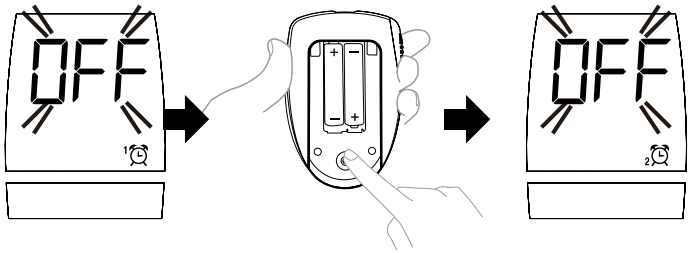
- The time, date and unit of measurement can ONLY be changed in the setting mode. Therefore, when you perform a glucose testing, those parameters are not possible to be changed.
- The meter cannot automatically update daylight saving time. You have to manually adjust the time in the meter according to the procedures. Please make sure the meter matches the time zone and adjust the daylight saving time data if required.
- Your meter displays 7-, 14-, 21-, 28-, 60- and 90-day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7-, 14-, 21-, 28-, 60- and 90-day preceding the current date and time settings. When the date and time are changed, the 7-, 14-, 21-, 28-, 60- and 90-day averages may change.
- While the meter is in the setting mode, it will turn off automatically without any action in one minute.

STEP 9 Select and Set Alarm Function

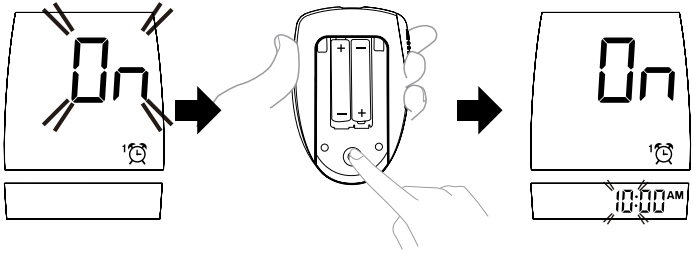
The meter provides four alarms. You are able to set four different alarming times a day. Flashing “On” or “OFF” and “ 1 2 3 4 ” are displayed on the screen firstly. Press the main button to turn on or turn off Alarm 1.

Alarm 1 setting

If you press the main button to select “OFF”, then press the set button to go to set Alarm 2.

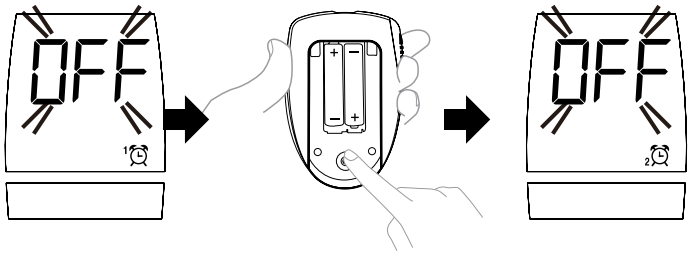


If you press the main button to select “On”, then press set button to set hour. While the hour is flashing, press the main button to plus an hour, and then press the set button. Blinking minute is displayed on the screen. Press the main button to advance one minute. To move faster, keep pushing the main button down. When the desired minute is displayed, press the set button to proceed to the next alarm setting.

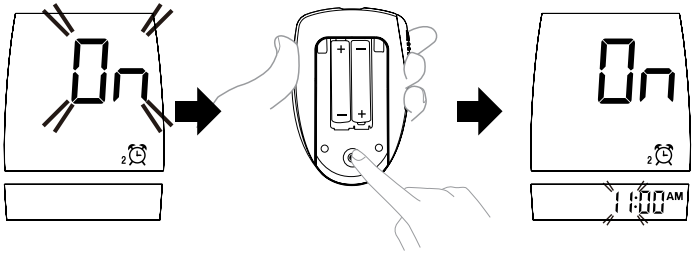


Alarm 2 setting

If you press the main button to select “OFF”, then press the set button to go to set Alarm 2.

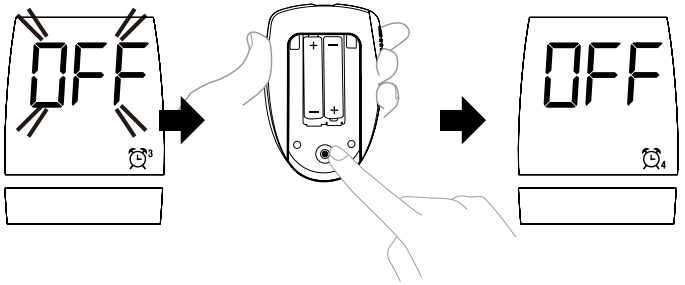


If you press the main button to select “On”, then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. After finished, press the set button to go to set Alarm 2.

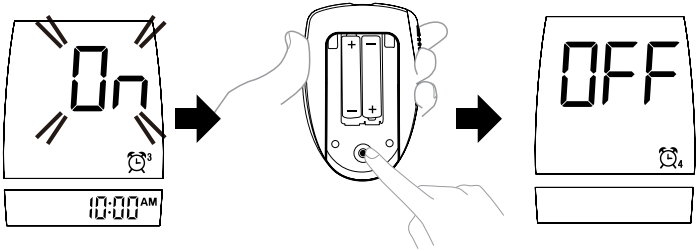


Alarm 3 setting

If you press the main button to select “OFF”, then press the set button to go to set Alarm 4.

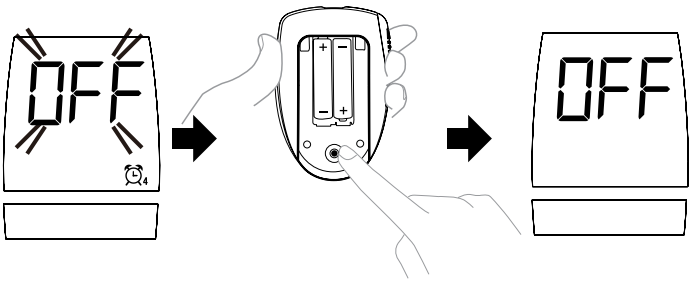


If you press the main button to select “On”, then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. After finished, press the set button to go to set Alarm 4.

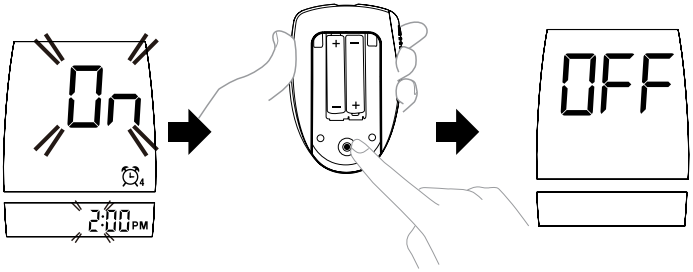


Alarm 4 setting

If you press the main button to select “OFF”, press the set button to turn off the meter.

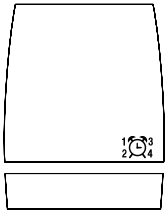


If you press the main button to select “On”, then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. After finished setting Alarm 4, press set button to turn off the meter.



Alarm Function

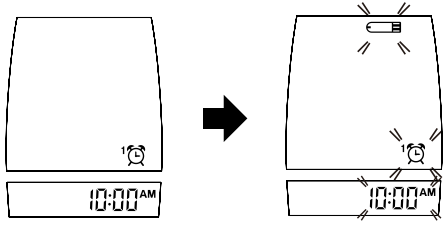
The meter provides for alarms. The alarm function alerts you to perform your blood glucose regularly. If you need to set alarm function, please refer to page19 " Select and Set Alarm Function" for information.



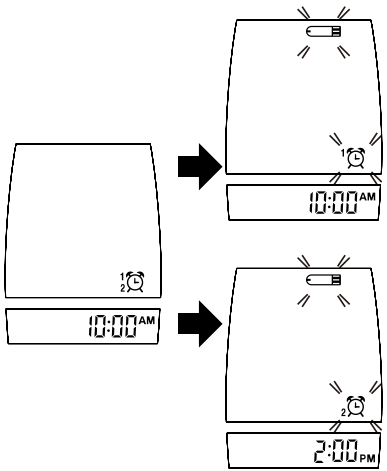
If you have turned on the alarm function, the meter will auto-start in the time point you set with short beeps for two minutes.

An example if set Alarm 1 at 10:00AM.

The meter automatically turns on at 10:00 AM everyday with beeping for two minutes, blinking " ▭ " and 1 2 3 4. You can directly insert a new strip to perform blood glucose test now.

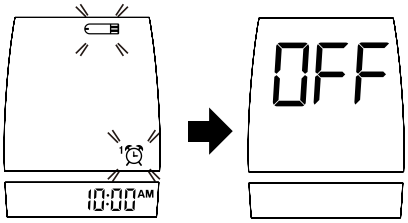


An example if Alarm 1 at 10:00AM and Alarm 2 at 2:00PM.
The meter automatically turns on at 10:00 AM first and next turns on at 2:00 PM. You can directly insert a new strip to perform a test.



If you don't want to perform a test after the meter turns on:

►Press the main button. "OFF" displays and then the meter will turn off.



► Or you can leave the meter without pressing any button for two minutes. The meter will turn off automatically

PLEASE NOTE!

- If the alarm function is set, the alarm symbol will appear on the screen when the meter is off.
- Each alarm setting function is independent, you can set alarm function separately and the setting will not affect other alarm function.

◉ BEFORE TESTING

◈ Checking with UltraTRAK PRO Glucose Control Solution

UltraTRAK PRO glucose control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, it is able to check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

How often the control solution test should be performed?

When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.

For routinely check the meter and test strips, perform a single test for each level of control solution at least once a week.

When the control solution test should be performed?

- When you first get your meter.
- When you begin using a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.

- When your test strips are exposed to extreme environmental conditions (See **Storage** section of this manual).
- When you want to practice running the test.
- If you drop the meter.

◈ Important Control Solution Information

- Use only UltraTRAK PRO control solutions.
- Check the expiration date on the control solution vial. Do not use if expired.
- Control solution, meter, and test strips should come to room temperature 68°F to 77°F(20°C to 25°C) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.
- Store the control solution tightly closed at temperatures 36°F to 86°F (2°C to 30°C). Do not freeze.

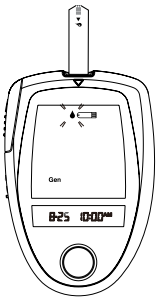
PLEASE NOTE!

The control solution range printed on the test strip vial is for UltraTRAK PRO control solution only. It is used to test meter and test strip performance. It is not recommended range for your blood glucose level.

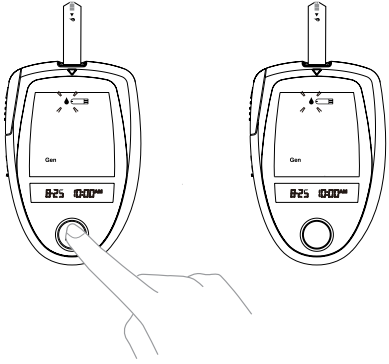
◈ Doing a Control Solution Test

STEP 1 Insert the Test Strip
Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the followings in sequence:

→ ”CHK” and “ ▭ ”
→ ambient temperature
→ ▭ , flashing ♦ and "Gen".



STEP 2. Press the main button
While the “ ♦ ” symbol is flashing, press the main button and you will see the “QC” appear, which means that the meter is in the “Control Solution Testing Mode”. If you decide not to perform a control solution test, press the main button again and the “QC” sign will disappear.

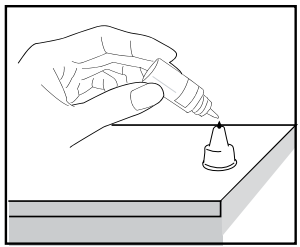


WARNING

- Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.
- Every time you perform a control solution test, you must enter into the “QC” test mode and then the test result with “QC” symbol will be stored in the meter memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.
- The control solution test with QC symbol can be stored in meter memory, but not be calculated to the average results.

STEP 3 Obtain Control Solution.

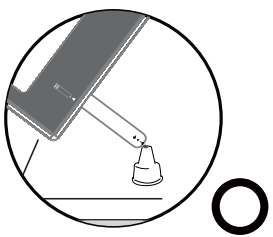
Shake the control solution vial well. Remove the cap from the control solution bottle. Place cap on flat surface. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and **apply the drop to the top of cap.**

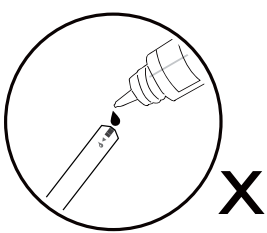


STEP 4 Apply Control Solution.

While holding the meter, move the absorbent hole of the test strip to touch the drop of control solution. Then the drop will be automatically drawn into the test strip. Make sure the confirmation window fills completely. The meter begins to count down.

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface. Do not directly apply control solution into a strip.





STEP 5 . Read and Compare the Result

After counting to 0, the test result of control solution is shown on the screen.Compare this result with the range printed on the test strip vial. It should fall within this range.

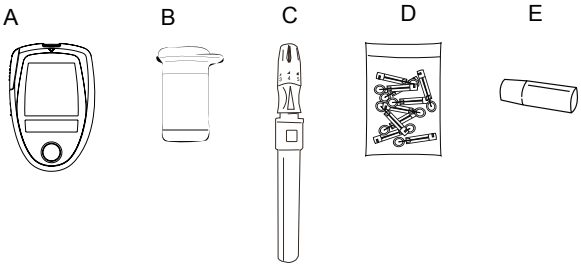
Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of “Problem in Operation” in trouble-shooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood. Please contact the Customer Care Line at 1.888.90.VERTEX

TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

A.Blood Glucose Meter
B.Test Strip
C.Lancing Device
D.Sterile Lancet
E.Clear Cap (For AST use)



WARNING

To reduce the chance of infection:

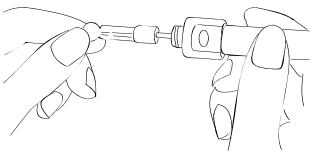
- Never share a lancet or the lancet device with others.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancet device.

◈ Testing Procedure

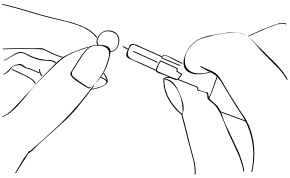
Wash and dry your hands first before starting.

STEP 1 Set the Lancing Device.

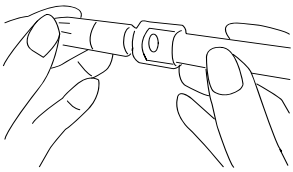
Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



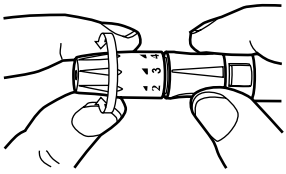
Twist the protective disk until it separates from the lancet.



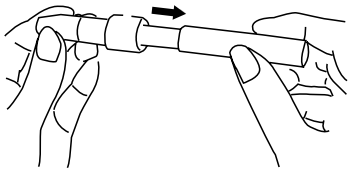
Replace the lancet device cap. Turn the cap until it is snug but not too tight.



Twist the adjustable tip in either direction until the number lines up with the Arrow: The adjustable tip offers 5 levels of skin penetration. 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin.

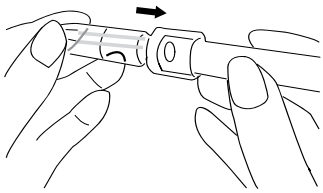


Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.



- **Blood from sites other than the fingertip**

A clear cap, together with the kit, makes it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, replace the lancing device cap with the clear cap. Turn the clear cap until it is snug but not too tight, and then slide the ejection/cocking control back until it clicks.



The lancing device is now ready for use. Set aside for later use.

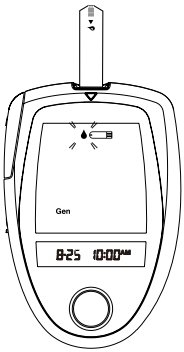
STEP 2 Insert Test Strip

Insert a test strip with contact bars end first and facing up into the test slot. The meter turns on automatically and displays the followings in sequence:

→ ”CHk” and ” ”

→ ambient temperature

→ , flashing and "Gen"

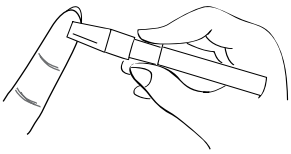


STEP 3 Get a Drop of Blood

Select the puncture site either in finger or in other parts (AST). Clean the puncture site with 70% alcohol cotton and **let it air-dry**.

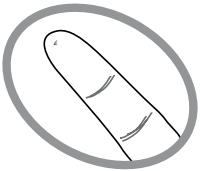
➢ **Fingertip**

Hold the lancing device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete.

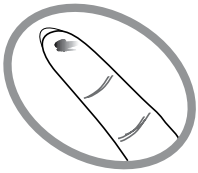


➢ Sites other than fingertip

Please refer to the section of "About AST" for available punctured sites.



O Correct



X Incorrect

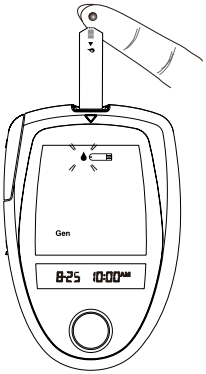
After penetration, discard the first drop of blood with a clean tissue paper or cotton. Then gently squeeze the punctured area to obtain blood. But be attention **NOT to smear the blood sample.**The volume of blood sample must be at least 0.7 microliter (· actual size).

PLEASE NOTE!

- Choose a different spot each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- Before you decide to do AST, please consult your health professional firstly.
- Since the first drop of blood usually contains tissue fluid and serum, which may affect the test result, it is recommended to be discarded.

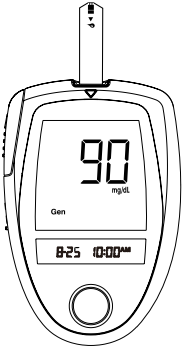
STEP 4 Apply Blood into the Test Strip

When " 🩸 " is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is **fully filled** with blood. The meter then begins to count down automatically.



STEP 5 Obtain an Accurate Result in 7 Seconds

The result of your blood glucose test is shown after the meter counts to 0. This reading is automatically stored in the meter.

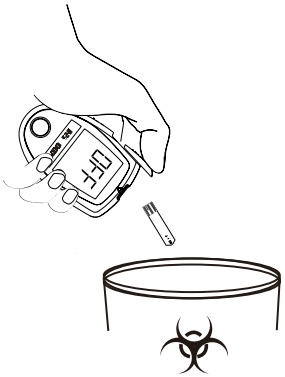


PLEASE NOTE!

- Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to restart the test procedure.
- The blood should be completely filled the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting. **NEVER** try to add more blood to the test strip. **Discard the test strip and retest with a new one.**
- If you have trouble filling the test strip, please contact the Customer Service Line for help.

STEP 6 Eject the Used Test Strip

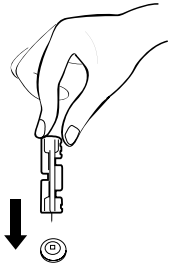
After finishing the measurement, you can either take out the used strip by simply pushing up the Strip-Ejection button or remove the test strip directly by your hand. “OFF” is shown after the used strip is ejected and the meter will shut off automatically afterward.



STEP 7 Remove the Lancet

Always use caution when removing the lancet.

Take the lancet out carefully. Place the disk on a hard surface and push the exposed tip into the protective disk.



WARNING

The used lancet and the used test strip may be potentially biohazard. Please discard it carefully according to your local regulations.

◈ Expected Test Results

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that **keeping blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%*[1]. The results you get with the UltraTRAK PRO system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Plasma glucose range for people without diabetes	Your target range (mg/dL)
Fasting and before meal*[a]	70-110mg/dL (3.9-6.1 mmol/L)	
2 hours after meals*[b]	Less than 140mg/dL (7.8 mmol/L)	

*a: Sacks,DB in " Carbohydrates ", Burt, CA, Ashwood,ER(ed), Tietz Textbook of Clinical Chemistry, Philadelphia, WB Saunders Company, 1999.

*b: ADA Clinical Practice Recommendations 2003

*1: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

Please work with your doctor to determine a target range that works best for you.

◉ COMPARING METER AND LABORATORY RESULTS

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way (See test strip package insert for typical accuracy and precision data, and for important information on Limitations). To make an accurate comparison between meter and laboratory results, follow the guide-lines below. .

Before you go to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- It is best to fast for at least eight hours before doing comparison tests.
- Take your meter with you to the lab.

While at the lab:

Make sure that the samples for both tests (the meter test and the lab test are taken and tested within 15 minutes of each other).

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress*[2]. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test*[3]. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*3: Sacks, D.B.: “Carbohydrates. “ Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Com pany (1994), 959.

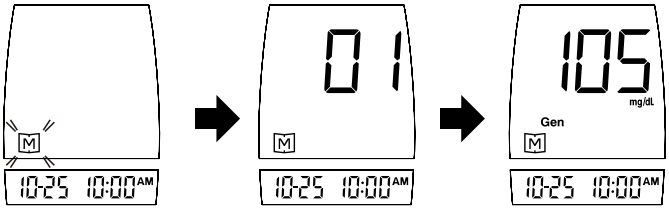
◉ USING THE METER MEMORY

◈ View Results on the Meter

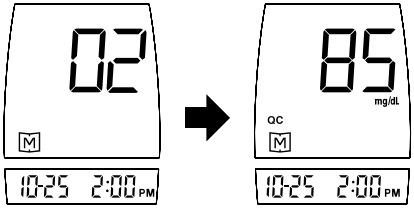
Your meter stores the latest 450 results of control solution and your blood glucose with date and time in its memory. It also automatically calculates the averages of your blood glucose in the intervals of 7, 14, 21, 28, 60 and 90 days. You can review the results easily by the following steps.

1. Recall the Stored Test Results

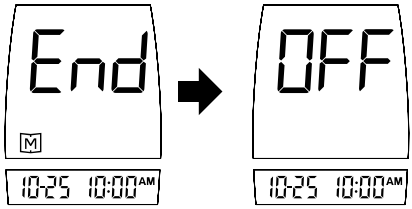
STEP 1. When the meter is off, press and release the main button. The screen shows " Ⓜ ". Press the main button again, "01" appears first and then the latest glucose result along with date and time will be shown on the screen.



STEP 2. Press the main button once by once to recall the test results stored in the meter consecutively.

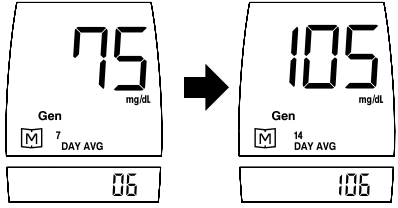


STEP 3. After the last test result, press the M button again and the meter will be turned off.

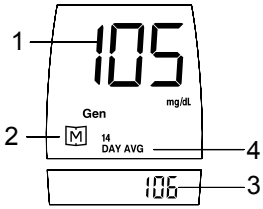


2. Read the Average of Blood Glucose Results:

STEP 1. When the meter is off, press and release the main button. The screen shows " M ". Keep pressing the M button for 2-3 seconds, until blinking "DAY AVG" appears. Release the main button and then the 7-day average result will appear on the screen.



The 7- day average is calculated from the blood glucose results obtained during the last 7 days.

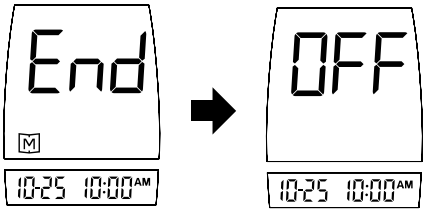


① The average of glucose tests.
② The average was calculated from the test results of the last 14 days.
③ 106 glucose tests have been performed in the last 14 days.
④ You can interpret the figure as: The average of 106 glucose test in the last 14 days is 105 mg/dL

STEP 2. Press the main button once by once to review the 21-, 28-, 60- and 90- day average in order. Like the 14-day average, the 21- day average and the times of performing test in the past 21 days will be shown on the screen.

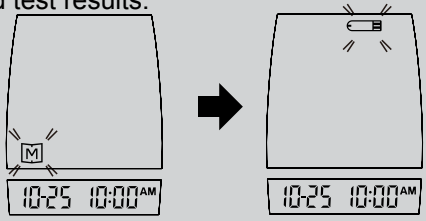
STEP 3. Exit The Memory Mode

After the 90-day average, press the main button again to turn off the meter.

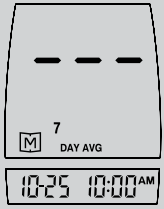


PLEASE NOTE!

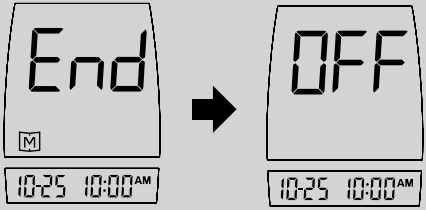
1. When pressing the main button to recall the stored test results, blinking " M " will be displayed on the main screen first. If you do not press the main button within 5 seconds, the blinking " ▭ " will appear. In the meantime, you can choose to insert a test strip to start testing your blood or to press the main button again to review the stored test results.



2. When using the meter for the first time, "---" is displayed when you recall the test results or review the average result. It means that there is no test result in memory.



3. Anytime when you want to exit the memory, keep pressing the main button for 5 second until "OFF" displays. The meter then automatically shut down.



4. If no button is pressed within 2 minutes, the meter will show "OFF" and turn off automatically.

5. The control solution results with QC symbol and blood glucose results with Gen symbol are stored in the memory (please also go to page 32 WARNING for information). But the average result is for blood glucose results only.

◉ VIEWING RESULTS ON A PERSONAL COMPUTER

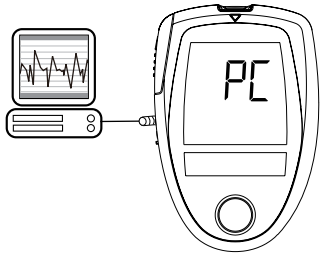
Results in memory can be transmitted to the personal computer. Health Care System Software and an Interface Cable are required before installation. The software can be downloaded from the home page of Vertex Diagnostics (www.vertexdiagnostics.com). The interface cable is an optional accessory. To learn more about Health Care System Software or to obtain an Interface Cable separately, please contact your local customer care line.

Step 1 Install Software

Install Health Care System Software on your computer by following the instructions provided on Vertex's website: http://www.vertexdiagnostics.com

Step 2 Connect to Personal Computer

Connect the interface cable to a serial port of your computer. With the turned off, connect the Interface Cable to the Data Port of the meter. "PC" will appear on the display, indicating that the monitor is ready to transmit data



Step 3 Transmit Data

Follow the instructions provided in the software to transmit data. Results transmitted will include date and time. Remove the cable and the meter will automatically turn off.

PLEASE NOTE!

While the meter is connected to the PC, it is unable to perform a blood glucose test.

◉ TAKE CARE OF YOUR METER AND STRIP

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

◈ Cleaning

1. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the meter.

◈ Storage

1.Meter Storage

■ Storage condition: -4 to 140°F (-20 to 60°C), below 95% relative humidity.

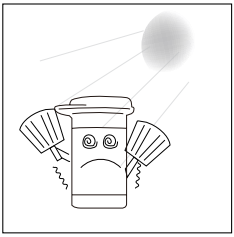
■ Always store or transport the meter in its original storage case.

■ Avoid dropping and strong impact.

■ Avoid direct sunlight and humidity.

2. Strip Storage

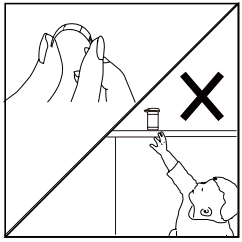
- Storage condition: 40°F to 140°F (4°C to 40°C), below 85% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to other container.



- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Touch the test strip with clean and dry hands.

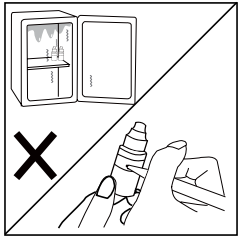
- Use each test strip immediately after removing it from the vial.
- Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.

- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.



3. Control solution storage

- Storage condition: Store the control solution tightly closed at temperatures 35.6°F~86°F(2°C~ 30°C). Do not freeze.
- Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.



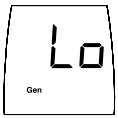
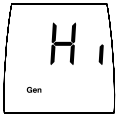
◉ PROBLEM-SOLVING GUIDE

The “Error Messages” you will probably encounter when using this meter are listed as followings. If you get any problem in performing test with this meter, please refer to the following problem-solving guides. These guides help you to identify and solve certain problems, but not in all circumstances. Improper use may cause inaccurate results without showing any error message or symbol. In the event of a problem, refer to the information under action.

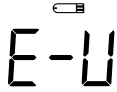
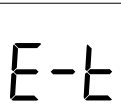
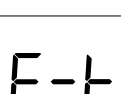
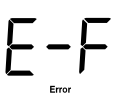
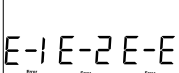
Never try to disassemble the meter in any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem keeps unsolved, please contact the Customer Care Line at 1.888.90. VERTEX

◈ Special Message

Special symbols and messages appear together with your test result.

Message	What it means
	Lo appears when your result is below 20 mg/dL (1.1 mmol/L).
	KETONE? is shown when your result is equal or higher than 240 mg/dL (13.3 mmol/L). This indicates the possibility of ketone accumulation for Type 1 diabetes. Please seek medical assistance immediately.
	Hi is displayed when your result is higher than 600 mg/dL (33.3 mmol/L).

◈ Error Message

Message	What it means	Action
	Appear when the battery can not provide enough power for a test.	Replace the battery immediately.
	Appear when inserting a used test strip.	Test with a new test strip.
	Appear when environmental temperature is below system operation range: 50°F (10°C).	System operation range is 50 to 104°F (10 to 40°C). Repeat the test after the meter and test strip have reached the above temperature.
	Appear when environmental temperature is above system operation range:104°F (40°C)	
	Remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip.
	Problem with the meter.	Review the instructions and re-test with a new test strip. If the above steps do not work, please contact the dealer.

◈ Problem in operation

1. If the meter does not display a message after inserting a test strip:

PROBABLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Battery incorrectly installed or absent.	Check that the battery is correctly installed.
Test strip inserted upside down or incompletely.	Insert the test strip correctly with the contact bars end first and facing up.
Defective meter.	Please contact the Custome Care Line at 1.888.90.VERTEX

2. If the test does not start after applying the sample:

PROBABLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Did not apply sample until "🩸" is flashing.	Repeat the test with a new test strip. Apply sample only when " 🩸 " appears on the display.
Defective meter.	Please contact the Customer Care Line at 1.888.90.VERTEX

3. If the control solution test result is out of range

PROBABLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instruction thoroughly and repeat the test again.
Do not shake the control solution vial very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date or the discarded date of the control solution.
Control solution that is too warm or too cold.	Control solution, monitor, and test strips should come to room temperature 68°F to 77°F (20°C to 25°C) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Meter malfunction.	Contact the Customer Service Line at 1.888.90. VERTEX

◉ SPECIFICATIONS

Dimension & Weight: 61.7mm(L) x 92.7mm(W) x 23.2mm(H), 79.97g

Power source: two 1.5V AAA alkaline batteries
Memory: 450 measurement results and control solution tests with date and time
Auto electrode inserting detection
Auto sample loading detection
Auto reaction time count-down
Auto turn-off after 3 minutes without action
Temperature warning
Operating condition: 50°F to 140°F (10°C to 40°C), below 85% R.H. (noncondensing)
Storage/Transportation condition: -4 to 140°F (-20 to 60°C), below 85% R.H.
Measurement Units: Either mg/dL or mmol/L
Measurement Range: 20~600mg/dL (1.1~33.3mmol/L)

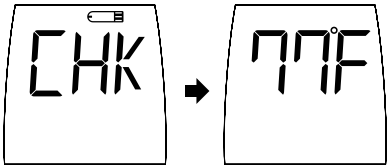
The device has been certified to meet the electrical and safety requirements of:
IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326.

◉ SUMMARY OF OPERATION

This summary is intended only for quick reference and not as a substitute for the owner's manual. Please read the entire manual before you begin testing.

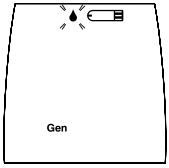
STEP1. Insert test strip

The meter is automatically turned on.
The room temperature is also displayed.



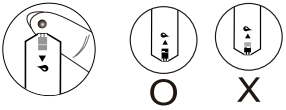
STEP2. Verify Display

The meter will immediately display a " ♦ " and the strip.



STEP3. STEP3.Puncture and apply sample

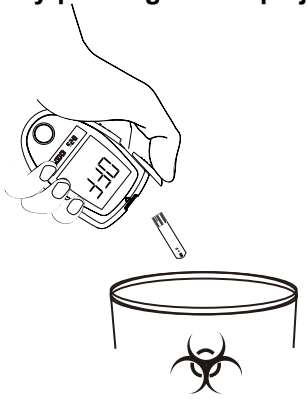
Touch and hold the drop of blood to the absorbent hole of test strip until confirmation window is completely filled.



STEP4. STEP4.Obtain a result

The meter starts to count down. Never try to add any blood into the absorbent hole even if you find that the confirmation window is not completely filled.
Discard the strip and retest with a new strip.

STEP 5 Eject the used strip by pushing the strip-ejection button.



STEP 6. Discard the used strip and the lancet according to your local regulations

Distributed by:
Vertex Diagnostics
958 Church St.
Baldwin, NY 11510
USA
Customer Care Line: 1.888.90.VERTEX

Customer Service Line is available for 24 hours, 7 days a week.

Note

Note

Note

Note